K113346

FEB 2 8 2012

ulrich medical USA

510(k) Summary

Date:	**10 November 2011**
Sponsor:	**ulrich GmbH & Co. KG** Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0) 731-9654-1304 Fax: +49 (0) 731-9654-2802
Contact Person:	Hans Stover ulrich medical USA, Inc. 612 Trade Center Blvd. Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Proposed Trade Name:	neon™
Device Classification	Class II
Classification Name:	Spinal interlaminal fixation orthosis
Regulation:	888.3050
Device Product Code:	KWP
Device Description:	neon™ is a modular, posterior system used for the surgical stabilization and fixation of the occipito-cervico-thoracic regions of the spine. If necessary, the occipito-cervical junction as well as the cervico-thoracic junction may be included. The system components include longitudinal members such as hybrid plate/rods and straight rods, anchors such as self-drilling and self-tapping screws and hooks, and interconnecting devices such as anchor-to-rod connectors and a rod-to-rod crosslink.
Intended Use:	When intended to provide immobilization and stabilization as an adjunct to fusion of the cervical spine and the occipito-cervico-thoracic junction (occiput-T3), the plate/rod, rod, hook, screw, connector and crosslink components of neon™ are indicated for the treatment of: • DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), • spondylolisthesis,

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- spinal stenosis,
- fracture/dislocation,
- atlantoaxial fracture with instability,
- occipitocervical dislocation,
- revision of previous cervical spine surgery, and
- tumors

The cortical (3.5mm) bone screws are limited to occipital fixation only.

The hook, rod and crosslink component placement is indicated for the cervical/upper thoracic (C1-T3) spine.

The use of neon screws (with easy fits), polyaxial connectors (with inlays and optional spacers) is limited to placement in the upper thoracic spine (T1–T3) for anchoring of the system. Screws are not intended to be placed in the cervical spine.

Materials: neon™ components are manufactured from titanium (Ti Grade 2, ASTM F67) or titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Devices: Ascent POCT System (K033480 and K073420)

Nex-Link OCT and Cervicothoracic Spinal System (K031985, K052566, K062505 and K090060)

CerviFix® System (K030377 and K011966)

Technological Characteristics: neon™ possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (rod-based having screw and/or hook anchors),
- material (titanium / titanium alloy),
- sizes (dimensions are comparable to those offered by the predicate systems) and

The fundamental scientific technology of neon ™ is the same as previously cleared devices.

Performance Data: Mechanical testing of the worst case neon™ constructs included static and dynamic compression bending according to ASTM F1717, and static and dynamic compression bending and torsion according to ASTM F2076.

The mechanical test results demonstrate that neon™ performs as well as or better than the predicate devices and therefore that the device is as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ulrich GmbH & Co., KG
% Ulrich Medical USA, Inc.
Mr. Hans Stover
612 Trade Center Boulevard
Chesterfield, Missouri 63005

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Re: K113346
Trade/Device Name: neon™
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: February 11, 2012
Received: February 14, 2012

Dear Mr. Stover:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113346

Indications for Use Statement

510(k) Number:_____

Device Name: **neon™**

Indications for Use:

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Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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